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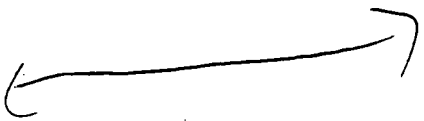
NSSC -

Draft OSWER Interim Risk Methodology for Asbestos



Briefing for R8

July 18, 2007

Stiven Foster

Objectives of Interim Methodology

- Provide a state of the science approach for quantifying asbestos cancer risk using TEM data
- Evaluate the potency associated with different classes of asbestiform minerals (amphibole or serpentine)
- Evaluate the potency associated with different fiber dimensions (length and width)

History of the OSWER Interim Risk Methodology

- OSWER has been working on this methodology for a number of years:
  - Initial work began in R9;
  - The Libby response re-ignited the effort;
  - In 2003, we conducted peer consultation on 2001 draft.
- Earlier drafts often called "Berman and Crump Methodology" because these contractors performed the initial work.

2003 Peer Consultation

- Eleven experts reviewed the draft methodology.
- Strongly endorsed approach:
  - That potential differences in potency associated with mineral type and particle size.
- They also recommended:
  - Increasing transparency and reproducibility;
  - Conducting sensitivity and uncertainty analysis;
  - Considering other bin definitions.

Need to Advance Methodology

- Parties inside and outside of the Agency have been using, or considering the use, of earlier drafts of this methodology.
- Changes are needed to address technical issues identified by EPA and the concerns of the 2003 peer consultation panel.
- The methodology needs to be peer reviewed before its use can be supported by EPA.

Overview of Interim OSWER Risk Methodology

- Based solely on meta-analysis of epidemiology studies
  - All studies with sufficient exposure-response data are considered
  - Probabilistic techniques (PDFs) are used to characterize the uncertainty and variability associated with each study
- Uses the same general models as the Airborne Asbestos Health Assessment Update (USEPA, 1986), which was used to derive the IRIS assessment
  - Relative risk model for lung cancer
  - Absolute risk model for mesothelioma

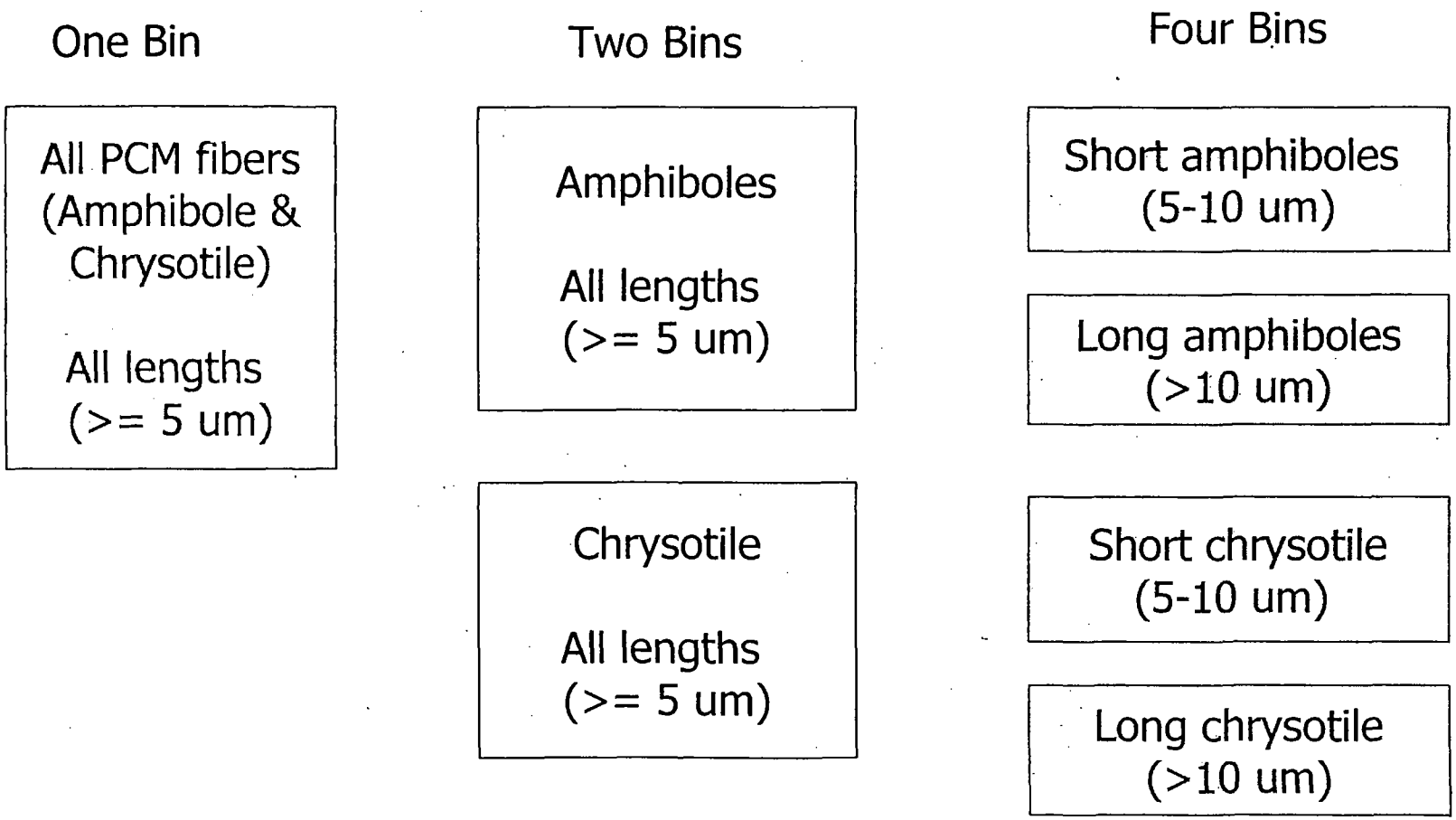
Use of Surrogate Data

- None of the available epidemiology studies used TEM to obtain particle size data.
- A set of studies that have employed TEM to characterize fibers in various work environments are used as a surrogate.
- The surrogate data allow us to develop a risk metric based on fiber size and type rather than on PCM fiber counts.

Multi-Bin Approach

- Influence of fiber dimensions and mineralogy on potency are evaluated using "bins"
  - For example, separate potencies are derived for bins of amphibole and serpentine fibers (see example)
- Evaluating 20 different strategies

Example of Binning Approaches



Binning strategies for 1-bin model

Designation	Mineral Type	Length (um)	Width (um)
1P	Amphibole and chrysotile	>5	>0.25
1A		>0	< 0.4
1B		>5	
1C		>10	
1D		>0	< 1.5
1E		>5	
1F		>10	

Binning Strategies for Two and Four Bins Models

Number of Bins	Designation	Mineral Type	Length (um)	Width (um)
2	2P	Amphibole or Chrysotile	> 5	≥ 0.25
	2A		All	< 0.4
	2B		> 5	< 0.4
	2C		> 10	< 0.4
	2D		All	< 1.5
	2E		> 5	< 1.5
	2F		> 10	< 1.5
4	4A	Amphibole or Chrysotile	0-5 > 5	< 0.4
	4B		5-10 > 10	< 0.4
	4C		0-10 > 10	< 0.4
	4D		0-5 > 5	< 1.5
	4E		5-10 > 10	< 1.5
	4F		0-10 > 10	< 1.5

Note: The seven binning strategies presented for two bin model were also examined for one bin model.

Method for Applying Surrogate Exposure Data

Published bi-variate TEM size data from matched workplaces are used to partition the PCM-exposure into bin-specific values, as follows:

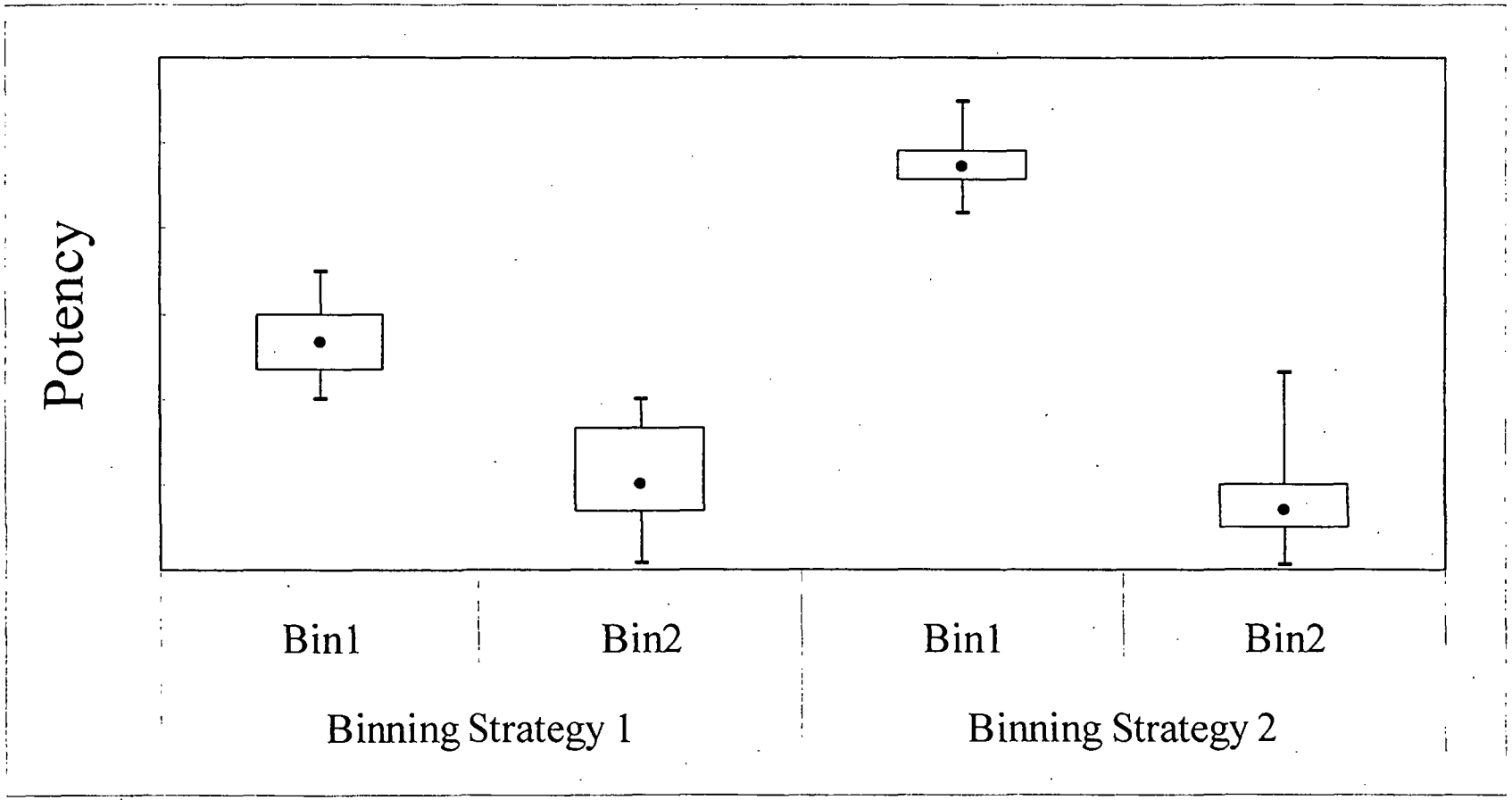
$$Ci = CPCME \cdot fi / fPCME$$

where:
CPCME = concentration of phase contrast equivalent structures

fi = fraction of all TEM fibers that meet the definition of Bin

fPCME = fraction of all TEM fibers that meet the definition of PCME

Comparison of Binning Strategies



Model Inputs

- Requires site specific characterization of exposure environment by TEM, including:
  - Proportion amphibole/chrysotile
  - Particle size distribution

Model Outputs

- Uncertainty distributions for each bin-specific potency factor
- Uncertainty distributions for mixture-specific potency factors
- Risk management or policy decisions could guide the selection of potency estimates from uncertainty distribution (mean and/or upper-bound)

Example Mixture-Specific Potency Factor Uncertainty Distributions

10 long: 1 short

Based on a ratio between short and long fibers equal to 10 1

3 long: 1 short

Based on a ratio between short and long fibers equal to 3:1

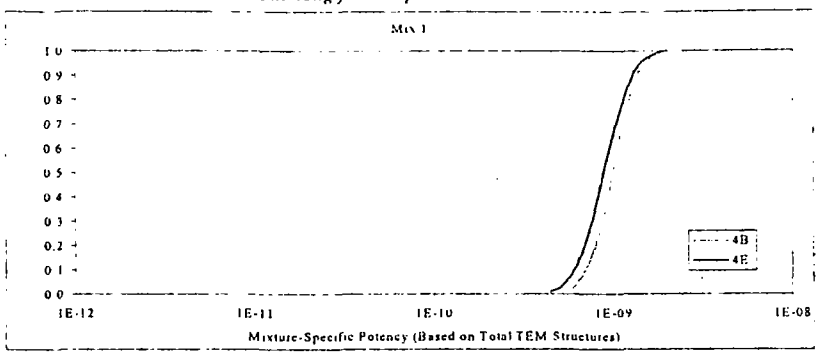
Fraction Amphibole

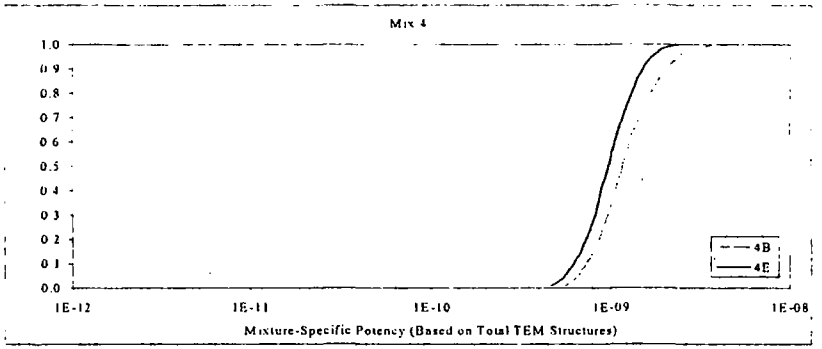
95%

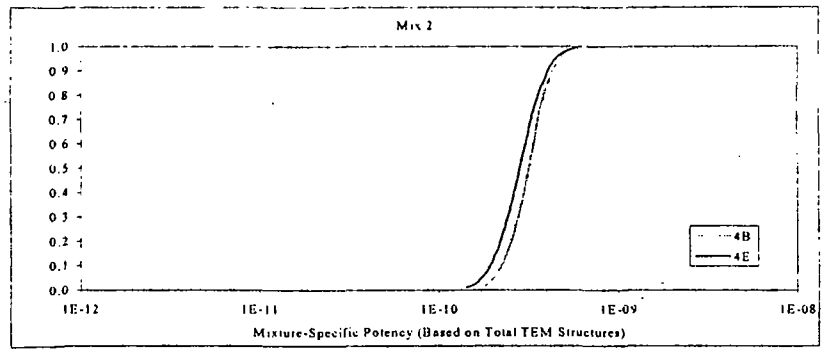
30%

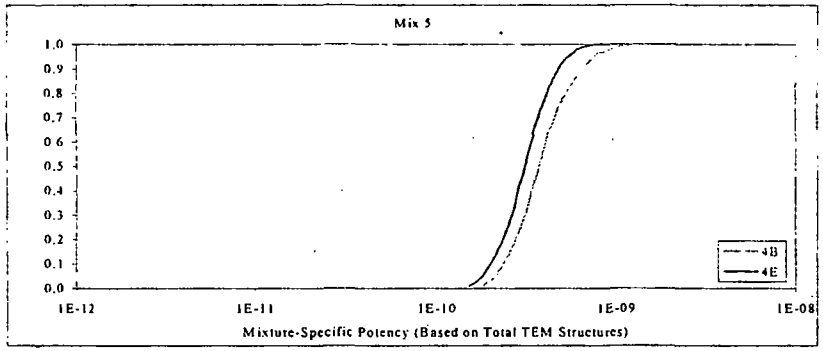
1%

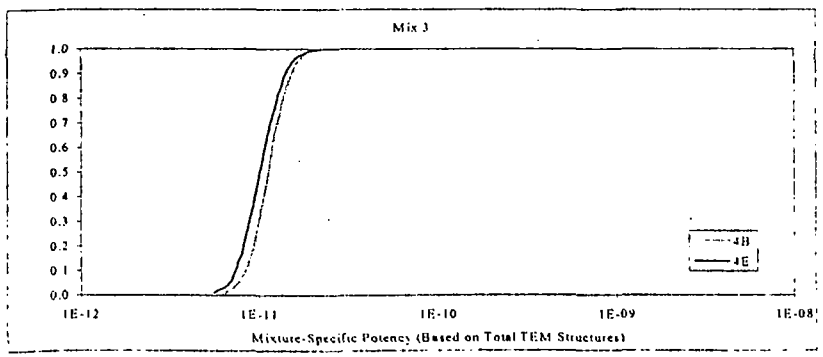
Y-axis = Cumulative Probability

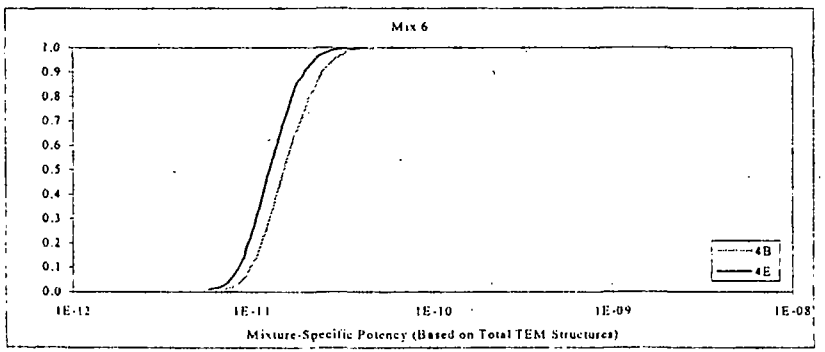








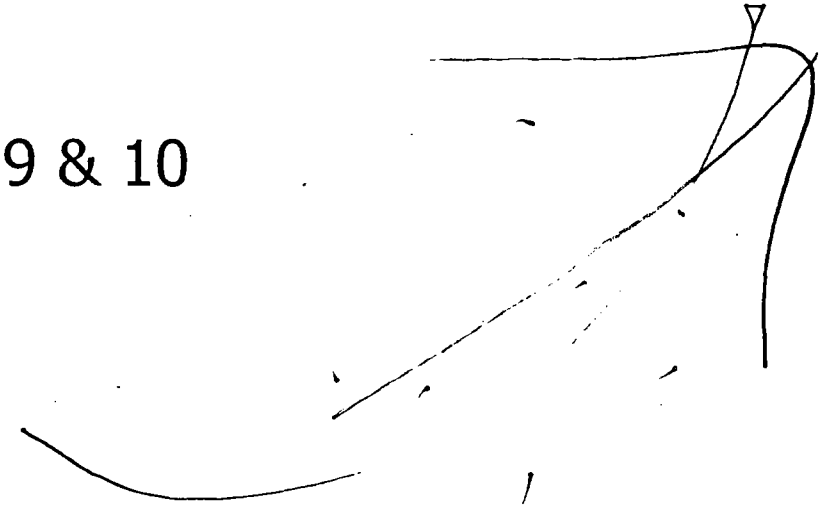




X-Axis = Mixture –Specific Potency for **mesothelioma**

Intra-agency Review

- Workshop was held in Sept. 2006 to discuss technical aspects of the methodology
- Review comments were received in October 2006 from:
  - ORD
  - OAR
  - Regions 9 & 10
  - ATSDR



Changes in response to intra-agency review comments

- Clarified purpose/intent of document
- Developed improved statistical procedure for comparison of different binning strategies
- Implemented one-step fitting of study-specific α terms in lung cancer studies
- Improved method for specifying uncertainty in cumulative exposure values

Changes - Continued

- Added greater detail on selection of fraction amphibole terms, and added sensitivity analysis for this term
- Added more detailed descriptions of epidemiological studies, plus more detailed descriptions of why some studies could not be used
- Enlisted the assistance of an expert epidemiologist (Marty Kanarek, University of Wisconsin) to assist with review and data selection from epidemiological studies

Libby Action Plan

- Participants at the Libby research planning meeting in January 2007 affirmed the need to finalize the methodology
- Included in the list of projects for the Libby action plan
- Development of Libby-specific cancer will further delay update of IRIS assessment

Communication with Other Organizations

- Presentations made or planned for:
  - SPC and its asbestos subcommittee
  - ATSDR
  - Interagency Asbestos Workgroup
  - Program and regional office briefings are being conducted
- Members of the Interagency Asbestos Workgroup will participate in the development of charge questions for SAB peer consultation

SAB Peer Consultation

- Federal Register notice to form panel issued in August 2006
- Anticipate selected panel members will be posted on SAB website in the near future
- Peer consultation meeting with SAB tentatively planned for September/October 2007

Next Steps

- Following peer consultation, OSWER will make necessary modifications
- Conduct a formal interagency review
- SAB peer review of the methodology

ATTACHMENT A **(Revisions in Bold)**

AMENDED
SCOPE of WORK
for
THE UNITED STATES GEOLOGICAL SURVEY

The USGS will provide timely technical assistance to the responsible EPA official or On-Scene Coordinator (OSC) for emergency response and time critical removal investigations and analyses.

The USGS will utilize its resources in providing geological services to the USEPA. It will review, analyze, and evaluate information obtained by itself as well as supplied by others in such disciplines as geology, hydro-geology, hydrology, geophysics, and water quality.

As requested by the USEPA, it will provide evaluations of data on seismicity, fracture flow pathways, geologic mapping, remote sensing, and other methods in determining the geologic risk involved at various site clean-ups.

The USGS will also provide other technical support for proposed removal actions as agreed upon by the agencies. **In addition, and in agreement between the agencies, specialized equipment may be purchased for use in analyzing data for various site clean-ups. Subsequent to competitive purchase procedures, USGS will operate and maintain the equipment for use on USEPA site cleanups.**

The USGS will also provide other technical support for proposed removal actions as agreed upon by the agencies.

For each project authorized by this IAG the USGS shall submit interim project reports detailing the progress to date as well as a final project report. The frequency of the interim reports shall be determined and agreed to by the On-Scene Coordinator and the Project Engineer representing the USGS. These reports will be distributed to the EPA Project Manager and all other interested parties.

Libby FY-07 Additional Expenditures

	Pipeline to Date	RA to Date	Pipeline FY-07	RA FY-07	Total 07
CVCC	$4,500.00	$0.00	$90,000.00	$0.00	$90,000.00
Creek Assessment	$2,000.00	$500.00	$16,000.00 ?		$16,000.00
Creek ABS (ERT)	$0.00	$0.00	$50,000.00	$0.00	$50,000.00
HelenAir/Spectra Issue	$75,000.00	$0.00	$75,000.00	$0.00	$75,000.00
ERS	$42,000.00	$60,500.00	$84,000.00	$120,000.00	$204,000.00
ERS to Demos	$0.00	$0.00	$0.00	$330,000.00	$330,000.00
Dust Pilot	$62,500.00	$0.00	$68,500.00	$0.00	$68,500.00
TAU Supplement/Lab Buildout	$75,000.00	$0.00	$105,000.00	$0.00	$105,000.00
TAG Grant	$50,000.00	$0.00	$50,000.00	$0.00	$50,000.00
Off Estimate of Baseline	$120,000.00	$260,000.00	$170,000.00	$450,000.00	$620,000.00
		Subtotal	$708,500.00	$900,000.00	
		Total			**$1,608,500.00**

Libby
FY-07 Cash Flow

INCOME

	Planned Budget	Amount Received	Amount Expected
Regional Pipeline	2,000,000.00	1,990,000.00	10,000.00
Regional Deobs	4,160,000.00	1,961,263.00	2,198,737.00
Remedial Action	17,000,000.00	14,700,000.00	2,300,000.00
Removal	500,000.00	500,000.00	0.00
ESAT	300,000.00	300,000.00	0.00
Toxicity Assessment	1,112,250.00	40,000.00	1,072,250.00
Total	25,072,250.00	19,491,263.00	5,580,987.00

Funds Out To Date

	Remdeial Action	Regional Pipeline	Regional Deobs	Removal	ESAT	Toxicity Assessment	Total
Volpe	14,700,000.00	482,231.00	1,961,263.00	400,000.00	0.00	40,000.00	17,583,494.00
USGS	0.00	0.00	0.00	0.00	0.00	0.00	0.00
SRC	0.00	170,973.00	0.00	0.00	0.00	0.00	170,973.00
ESAT	0.00	29,364.00	0.00	0.00	300,000.00	0.00	329,364.00
ERRS	0.00	0.00	0.00	100,000.00	0.00	0.00	100,000.00
Metheny	0.00	7,000.00	0.00	0.00	0.00	0.00	7,000.00
MDEQ	0.00	1,300,000.00	0.00	0.00	0.00	0.00	1,300,000.00
Total	14,700,000.00	1,989,568.00	1,961,263.00	500,000.00	300,000.00	40,000.00	19,490,831.00

Libby Cash Flow		
Item	**Amount**	**Comment**
ESAT Contribution	$300,000	Out of nat'l funds
Removal Contribution	$500,000	$400K in, $100K to come
Pipeline Contribution	$2,200,069	
Deobs to date	$3,696,343	
Total funds to date	**$6,696,412**	
Libby Commitment	$6,960,000	
Balance	**($263,588)**	
Available Deobs from RAC	$1,107,844	Deob memo awaiting OSRTI input
Paul's Supplemental Request	($838,000)	
Balance	**$6,256**	Subject to 75/25 policy